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APR 24 2007

Serial No.: 09/815,567 Filed: March 23, 2001

REMARKS

This paper is responsive to the Office Action mailed October 24, 2006. Claims 1-21 are pending in this application. All claims presently stand rejected. Claims 14 and 21 have been canceled. New claims 22 and 23 have been added to the application.

The present invention is directed to a flexible, kink resistant introducer sheath. A sheath that is flexible and kink resistant can be readily advanced through tortuous body passageways, and directed to target sites deep within the vasculature of a patient. As a sheath is advanced through tortuous body passageways, the sheath should preferably be able to maintain substantially all of its generally circular cross-section through as large a bending angle as possible. As long as the generally circular cross-section of the sheath remains at least substantially intact, the physician can deliver the largest possible medical interventional device, such as a stent, through the sheath for deployment at the target site.

When a sheath kinks, its cross-section collapses and the sheath is generally rendered useless for most intended purposes, such as the aforementioned passage of a stent through the sheath. In this event, the kinked sheath must be replaced with a new sheath. This adds unnecessary cost to the procedure, and increases the level of difficulty. It also increases the amount of time required to complete the procedure, if it can be completed at all. Providing a sheath having a coil reinforcement is advantageous because it enables the physician to negotiate tight bends in the vasculature, and in the process, reduce the incidents of failure when compared to the use of unreinforced sheaths, or sheaths equipped with other types of reinforcements, such as a wire braid.

In the Office Action, claims 1-2, 4, 9-11, 19 and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,792,124 to Horrigan, et al ("Horrigan"). Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan in view of U.S. Patent No. 5,380,304 to Parker ("Parker"). Claims 6-8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan in view of U.S. Patent No. 5,599,325 to Ju, et al. ("Ju"). Claims 12 and 13 were rejected under 35 U.S.C. §103(a) over Horrigan. Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan in view of U.S. Patent No. 6,210,396 to MacDonald, et al. ("MacDonald"). Claims 5 and 15-18 were rejected under 35

U.S.C. §103(a) as being unpatentable over Horrigan in view of U.S. Patent No. 6,159,187 to Park et al ("Park"). These rejections are referred to hereinafter as "Rejections Group 1".

Under what was described by the Examiner in the Office Action as an "alternative interpretation", claims 1-2, 4-5, 10-13 and 15-20 were also rejected under 35 U.S.C. §103(a) over Horrigan in view of Park. Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan in view of Park as applied to claim 1, and further in view of Parker. Claims 6-9 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Ju. Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of MacDonald. These rejections are referred to hereinafter as "Rejections Group 2".

Applicant's representatives appreciate the courtesies extended by Examiner Ramana and supervisor Eduardo Robert at the interview held on January 16, 2007, at the United States Patent and Trademark Office in Alexandria, Virginia. During the interview, Applicant's representatives argued the patentability of the claims, and discussed possible claim amendments. A computer animation that compared the respective bendability of two different sheaths, one having a braid reinforcement and the other having a coil reinforcement, was displayed. In addition, Declarant Thomas Osborne displayed a sample of sheath having a braid reinforcement and another having a coil reinforcement, and explained the differences between such reinforcements known to those skilled in the art. No agreement was reached at the interview. Applicant's representatives agreed to submit a revised declaration, and provide further evidence and arguments in support of the patentability of the claims in a subsequent response.

Rejections Group 1.

As stated above, claims 1-2, 4, 9-11, 19 and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by Horrigan. Claims 3, 5-8 and 12-18 were rejected under 35 U.S.C. §103(a) as being obvious over Horrigan in view of the secondary references recited above.

Claim 1 of the present application is directed to a flexible, kink-resistant introducer sheath. The sheath includes an inner tube extending to a distal end; a wire coil wound around the

inner tube extending to an end spaced proximally from the inner tube distal end; a first outer tube disposed around the wire coil and the inner tube therewithin to a first outer tube distal end spaced proximally from the wire coil distal end such that a distal end portion of the wire coil extends distally therebeyond; and at least a second outer tube disposed around the wire coil and the inner tube therewithin extending distally from the first outer tube distal end and covering the distal end portion of the wire coil and extending slightly beyond the distal end of the inner tube. The first outer tube is formed of a material having a relatively hard durometer, and the second outer tube is formed of a material of a substantially softer durometer than the material of the first outer tube.

Horrigan discloses a catheter or sheath having a lubricious inner liner, a wire braid reinforcement, a first outer tube and a second outer tube, wherein the second outer tube is made of softer durometer material than the first outer tube. The wire braid is a 16 strand stainless steel braid. Col. 4, line 23. Although Horrigan teaches a braid reinforcement rather than a coil as in the claimed sheath, the Examiner contends that a single strand of the 16 strand wire braid meets the limitation of a wire coil in claim 1.

Initially, Applicant respectfully takes issue with the Examiner's characterization of a single strand taken from a 16 strand braid as meeting the limitation of a coil. A single strand of wire in a woven braid includes, among other things, an undulating or serpentine-type configuration. This configuration results from the interweaving of the numerous wire strands that come together to define the woven braid. The undulating portions are typically present in, or result from, the areas of the wire that are subject to crossover and bending by the various other strands that combine to form the braid. Each crossover point creates an undulation, and thereby non-uniform spacing between adjacent turns of that strand. This is critical in providing the distribution of bending stress along the length of the sheath. A strand, when isolated from the remainder of the braid, thus includes such undulations which result in non-uniform spacing between the adjacent turns of the strand. A true coiled reinforcement, on the other hand, is structured in a manner such that the spacing is uniform between the turns. The bending and loading stress is thus distributed along the length of the sheath, without high concentration of stress at single points. Thus, for at least the foregoing reasons, Applicant submits that the isolation of a single strand of the 16 strand braid does not meet the limitation of a coil.

In addition to the foregoing, Applicant respectfully submits that even if a single strand from a woven braid can be considered to meet the limitation of a coil (a point that Applicant disputes), the present claims are still not anticipated by the Horrigan reference. In order to demonstrate that a patent claim is anticipated by a prior art reference under 35 USC 102, it must be established, among other things that there is "identity of invention" between the cited reference and the claim at issue. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771, 218 U.S.P.Q. 781, 789, cert. denied, 465 U.S. 1026, 224 U.S.P.Q. 520 (1984), overruled in part on another ground, *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1125, 227 U.S.P.Q. 577, 588-89 (Fed.Cir. 1985) (en banc). According to the Court, identity of invention is a question of fact, and one who seeks such a finding must show that each element of the claim at issue is found, either expressly or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice. *Id.*

In the present matter, the Examiner contends that a single strand of wire taken from the 16 strand braid meets the limitation of a coil. However, Applicant submits that much more than this is required to support an anticipation rejection. There is no identity of invention between the use of a braid reinforcement, or the isolation of a single wire strand from the braid, and the use of a coil reinforcement as in the claimed sheath. The respective braid and coil reinforcements are not considered interchangeable to those skilled in the art, and are provided for different purposes. See, e.g., Declaration of Thomas A. Osborne, filed in this matter May 3, 2004. According to the Osborne Declaration, when properties of a sheath, such as stiffness, pushability or torqueability are of paramount concern, a braid reinforcement is superior to a coil reinforcement. On the other hand, when it is desired to maximize the kink resistance of a sheath, a coil reinforcement is superior to a braid reinforcement. Declaration, paragraph 7. Therefore, when a single wire strand is wound as a part of a braided reinforcement of a sheath, the "identity" of that strand is as an essential part of a whole structure, i.e., a braid that is useful for increasing the stiffness or torqueability of the sheath. On the other hand, when a sheath is fitted with a wire coil reinforcement, the coil structure is provided to enhance the flexibility, or kink resistance, of the sheath. The single strand of a wire braid loses its identity as a stiffener when removed from the

remaining braided structure and substituted as a coil.

The relevant cases consistently hold that anticipation requires more than merely finding a structure somewhere in a compared device that can be said to correspond to a particular element in the claim. Rather, the proper focus is on the entirety of the invention. The accused prior art structure must be found in the same situation and arranged in the same manner as in the claimed structure. See, e.g., *Perkin-Elmer Corporation v. Computervision Corporation*, 221 U.S.P.Q. 669 (Fed. Cir. 1984).

As stated in *Ex parte Gould*, 6 U.S.P.Q. 2d 1680 (BPAI 1987), even if all elements of a claimed device are known and shown in a prior art reference (assuming *arguendo* that this is true in the present case), the elements in the prior art device must be arranged in the manner required by the claims. In *Gould*, the BPAI held that although certain elements of the claim may be found in the prior art reference, there is nothing in the reference that would give the artisan any reason to change the configuration in the reference to arrive at the claimed structure. Similarly, in *Akzo N.V. v. U.S. International Trade Commission*, 1 U.S.P.Q. 2d 1241 (Fed. Circ. 1986), the Court said that even though a certain prior art patent called for the use of sulfuric acid, it did not call for the more particularized use of at least 98% concentrated sulfuric acid, which was critical for the success of the claimed process. The Commission also concurred with the ALJ and found that concentrated sulfuric acid is not inherently 98% sulfuric acid to one skilled in the art.

These cases are relevant to the present claims because Applicant contends that even if, as the Examiner contends, a single strand of wire taken from a 16-strand braid meets the limitation of a coil, there is nothing in the Horrigan reference that would provide the artisan with any reason to change the configuration in the reference structure (having a braided reinforcement) to arrive at the claimed structure. Similarly, even though the prior art Horrigan reference teaches the use of a braid (a single strand of which arguably constitutes a coil), there is nothing in Horrigan that would lead the skilled artisan to the more particularized use of this strand as a coil reinforcement.

Other cases have also held that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention, arranged in the manner in which the element is arranged in the claim. In deciding the issue of anticipation, the trier of fact must

identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. See, e.g., *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al.*, 221, USPQ 481 (Fed. Cir. 1984). In *Lindemann*, the CAFC held that the district court's analysis erroneously treated the claims as mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning. Similarly, in *Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991), the Court held that invalidity for anticipation purposes requires that all of the elements and limitations of the claims be found in a single prior art reference, and that: "There must be no difference between the claimed invention and the referenced disclosure, as viewed by a person of ordinary skill in the field of the invention." *Id.*

In the present case, Applicant respectfully submits that a strand taken from the braided sheath in the cited Horrigan reference cannot support an anticipation rejection of the present claims without impermissibly treating the claims as mere catalogs of separate parts. Such a construction would disregard the part-to-part relationships set forth in the claim, and that gives the claim its meaning. Similarly, it is clear that one skilled in the art would not conclude that there is no difference between the claimed invention and the referenced disclosure, as viewed by a person of ordinary skill in the field of the invention. See, e.g., Osborne Declaration. Horrigan does not teach a sheath having a coiled reinforcement. As evidenced herein, there is a considerable difference between a sheath having a coiled reinforcement, and a sheath having a braided reinforcement, as taught in the allegedly anticipatory Horrigan reference. The omission of any teaching of a coiled reinforcement in the Horrigan reference changes the very character, or identity, of the structure taught by the reference.

Simply put, Applicant respectfully submits that the presence of a wire braid in the cited Horrigan reference is not sufficient to establish "identity of invention" with the claimed structure that includes a coil. When the cited cases are properly applied, it is clear that the anticipation rejection should be reconsidered and removed. Claims 2, 4, 9-11, 19 and 20 are dependent, directly or indirectly, on claim 1 and include all of its limitations, including the limitation of a coil reinforcement. Accordingly, these claims are also not anticipated for at least the same

reasons that claim 1 is not anticipated.

Claims 3, 5-8 and 12-18 were rejected as being obvious over Horrigan in view of the secondary references recited above. These claims are dependent, directly or indirectly, on independent claim 1, and include all of its limitations, including the limitation of a coil reinforcement. With regard to the secondary references, Parker was cited in the Office Action for its teaching of an inner tube having a roughed outer surface. Ju was cited for its teaching of an outer sheath tube made from a blend of a polymer and a radiopaque filler. MacDonald was cited for its teaching of an outer tube comprising first and second tube sections of different colors. Park was cited for its particularized description of a "braided wire coil" and an arcuate coil tip. Applicant respectfully submits that nothing in these teachings overcomes the shortcomings recited above with regard to the rejection of claim 1, and that these claims are allowable for at least the same reasons that claim 1 is allowable.

Rejections Group 2.

According to the Examiner's "alternative interpretation", Horrigan discloses a catheter or sheath having certain features in common with the claimed invention, but (according to this interpretation) does not teach the use of a coil as a reinforcement means. Park was cited for its teaching of a catheter section having a "braided wire coil", with particular reference made to Fig. 7 of Park. Thus, according to the Examiner, it would have been obvious to have substituted a "braided wire coil" as disclosed in Park for the wire braid of Horrigan.

As stated above, the present invention is directed to a flexible, kink resistant introducer sheath that may be used for, among other things, passing a stent therethrough for purposes of deployment within the vasculature. It is important to maintain the cross-section of the sheath intact, or substantially intact, through the largest bending angle possible, so that the physician can deliver the largest possible stent through the sheath to the target site. Providing a sheath having a coil reinforcement is advantageous, because a coiled sheath is capable of maintaining a cross-section sufficient for passing a stent therethrough throughout a much larger bending angle than a comparable sheath having a braid reinforcement.

As further support for the present claims, Applicant provides herein the Declarations of

Sathya Kaliyamoorthy, of ABAQUS Central, Inc., of Lafayette, Indiana, and Brett Baker, of Sabin Corporation, of Bloomington, Indiana. As stated in Kaliyamoorthy Declaration, ABAQUS was asked to design a computer simulation utilizing the technique of Finite Element Analysis ("FEA") to compare the kink resistance of a sheath designed to be representative of a sheath taught in Horrigan, to the kink resistance of a sheath otherwise similar to the sheath taught in Horrigan but having a coil reinforcement instead of the braid reinforcement disclosed in Horrigan. A first FEA model was designed to simulate the bendability of a sheath constructed according to the teachings of the Horrigan patent, having a wire braid formed of annealed stainless steel. A second FEA model was designed to simulate the bendability of another sheath constructed in accordance with the general teachings of Horrigan, but in which a wire coil formed of spring tempered stainless steel was substituted for the braided reinforcement. As explained in the declaration, each sheath model was "bent" to a progressively larger bending angle. The diameter of the sheath was monitored throughout the progression of the bending angles. This action was intended to simulate the behavior of the sheath when exposed to bending of a type that may be encountered as the sheath traverses a tortuous passageway in the vasculature. The Baker Declaration explains the use of an annealed wire in a braid reinforcement, and a harder (higher tensile) wire in a coil reinforcement.

As reported in the Kaliyamoorthy Declaration, the braid-reinforced sheath quickly began to lose its normalized diameter upon bending, and kinked at a bending angle of about 21 degrees. At this angle, the normalized stent diameter was reduced to about 0.6, or in other words, the circularity of the sheath was about 60% of normal diameter. Upon further bending the braid-reinforced sheath lost its entire diameter at a bending angle of about 47 degrees. On the other hand, at the same bending angle of 21 degrees, the coil-reinforced sheath maintained a circularity of about 96%. This sheath maintained a circularity in excess of 70% of the original diameter until reaching a bending angle of 67 degrees. Thus, it was demonstrated that the coil-reinforced sheath was able to be bent to a much greater angle (67 degrees vs. 21 degrees) than the braid-reinforced sheath, while maintaining a circularity greater than 70% of its original diameter. To place these results into a real-world application, since the coil-reinforced stent maintained a high percentage of its original diameter to a large bending angle (67 degrees), a stent having a

diameter approaching that of the normalized stent diameter of the bent sheath can be passed through the sheath, until the sheath is bent to an angle of 67 degrees. On the other hand, with a braid-reinforced sheath, the sheath loses much of its normalized stent diameter at a bending angle of only 21 degrees, and loses its entire diameter at 47 degrees. This sheath would have only limited utility for passage of a small diameter stent therethrough once it reaches a bending angle of 21 degrees, and would have no utility for such passage at 47 degrees.

The primary Horrigan reference teaches a guiding catheter for use in PTCA. According to the patent specification, it is an important characteristic of such catheters that they have sufficient stiffness to be pushed through vessels, as well as sufficient rigidity to provide a high degree of torsional control. Col. 1, lines 15-21. This is consistent with the use of a braid-reinforced sheath because, as stated in the Osborne Declaration referenced hereinabove, a braid-reinforced sheath is generally superior to a coil-reinforced sheath when properties such as stiffness and pushability are of paramount concern.

Although on one occasion in his patent, Horrigan refers to his design as providing kink resistance (a point that was noted by the Examiner in the instant Office Action), this comment was not provided in a context to compare the kink resistance provided by the braided Horrigan device to the kink resistance of a device that included a coil reinforcement, nor to extol the capability of the Horrigan device to traverse tortuous pathways. Rather, the point was merely made that some kink resistance may be obtained by a braided structure, under certain circumstances. In fact, the patent neither discusses this asserted "benefit" any further, nor provides any factual support for the underlying contention. As shown in the attached Kaliyamoorthy Declaration, a coil-reinforced sheath exhibits much greater kink resistance when compared to a braid-reinforced sheath.

The Horrigan reference neither teaches nor suggests an optimal manner of traversing a tortuous passageway, and in fact, by its use of a braided reinforcement, teaches away from such advantages. The secondary Park reference teaches a complex solution to the problem of providing access to a target site through increasingly small vessels. The solution to this problem advocated in Park differs considerably from the teachings of the present invention. Park utilizes a catheter having a section that is formable from a first form (or shape) to a predetermined

second form (or shape) upon the application of heat. The catheter includes within its wall a forming member, such as a super-elastic alloy, that is capable of distortion from the first shape to the second shape. According to the patent, the forming member is preferably a ribbon braid, because of "[its] ability to retain non-elastic strain and return to a prior form upon release of the polymeric restraint." Col. 7, lines 55-57. Park does not discuss any benefits in kink resistance that may be achieved when a coil reinforcement is utilized instead of a braid, and provides no reasons why one skilled in the art would want to use a coil. Although Park indicates that his device exhibits (among numerous other cited properties) kink resistance (Col. 2, lines 40-44), he also does not differentiate between a braid and a coil regarding this property. In fact, in view of Park's stated preference for a braid in his preferred embodiments, one skilled in the art might erroneously assume that a braided reinforcement provides better kink resistance than a coil reinforcement.

When confronting the problem of kinking that is often exhibited by a sheath when directed through tortuous passageways, one skilled in the art would not find the solution to this problem in either of the cited references, either individually or as combined by the Examiner. In fact, neither of the cited references exhibits any awareness of the significant benefits achieved with the use of a coiled sheath when traversing tortuous passages, and in each, the use of a braid is clearly preferred. Thus, Applicant respectfully submits that the combination of references cited by the Examiner in support of these rejections is insufficient to establish a prima facie case of obviousness of a coil-reinforced sheath of the type claimed herein.

Therefore, for all of the foregoing reasons, Appellant respectfully submits that claims 1-2, 4-5, 10-13 and 15-20, as amended, are not obvious in view of the cited combination.

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Parker (US 5,380,384). Claims 6-9 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Ju et al (US 5,599,325). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of MacDonald et al (US 6,210,396).

According to the Office Action, Parker was cited for its teaching of an inner tube having a roughed outer surface. Ju was cited for its teaching of an outer sheath tube made from a blend of a polymer and a radiopaque filler. MacDonald was cited for its teaching of an outer tube comprising first and second tube sections of different colors. Applicant respectfully submits that nothing in these teachings overcomes the shortcomings recited above with regard to the rejection of claim 1.

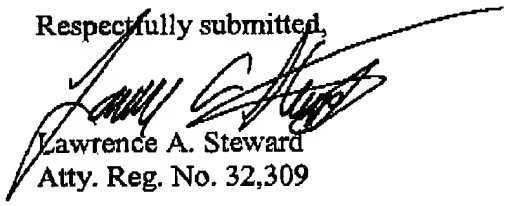
New claims

New independent claims 22 and 23 have been added with this response. Claims 22 and 23 include new claim language discussed with the Examiner at the interview. Specifically, claim 22 adds further description of the wire coil. According to this claim, the wire coil comprises a plurality of coil turns, "each coil turn being free of interference from another coil turn". This language is supported in the application, e.g., at Figs. 3 and 4. A braided reinforcement, such as the reinforcement in Horrigan, is fundamentally not free of interference from another coil turn.

New claim 23 includes an alternative description of the wire coil. According to this claim, the coil turns of the wire coil are free from being interwoven with another coil turn. This claim is also supported in the application, e.g., at Figs. 3 and 4.

Based upon the foregoing, Applicant respectfully submits that all claims 1-13, 15-20 and 22, 23 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a Notice of Allowance. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



Lawrence A. Steward
Atty. Reg. No. 32,309

BRINKS HOFER GILSON & LIONE
CUSTOMER NO. 48004
Phone: (317) 636-0886
Fax: (317) 634-6701